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### NOTICE OF ALLOWANCE AND FEE(S) DUE

36218 7590 12/17/2009
KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE #1600
PORTI AND OR 97204-2988

EXAMINER

KAUSHAL, SUMESH

ART UNIT PAPER NUMBER

1633

DATE MAILED: 12/17/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/534,626	05/11/2005 Toren Finkel		4239-67020-02	8541	
TITLE OF INVENTION; METHOD FOR DIAGNOSIS AND TREATMENT OF VASCULAR DISEASE					

ELOT INTENTION, METHOD FOR BIAGNOSIS AND TREATMENT OF VASCULAR BISLASI

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(8) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	03/17/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as

maintenance fee notifica	ttions.						arate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)			r	Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
36218	7590 12/17	72009	1				
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE #1600				Certificate of Mailing or Transmission  I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.			
PORTLAND, O	R 97204-2988		ſ				(Depositor's name)
			ľ				(Signature)
			į				(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENT	OR	ATTO	DRNEY DOCKET NO.	CONFIRMATION NO.
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nonprovisional	NO	\$1510	\$300	\$0		\$1810	03/17/2010
EXAM		ART UNIT	CLASS-SUBCLASS				
KAUSHAL	., SUMESH ence address or indicatio	1633	424-009100 2. For printing on the				
CFR 1.363).  Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  Tee Address indication for Tee Address' Indication form FTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			(2) the name of a si	t up to 3 registered patent attorneys termitwely, a single firm (having as a member a 2-cy or agent) and the names of up to it autoresty or agents. If no name is 3			
	less an assignee is ident th in 37 CFR 3.11. Comp	A TO BE PRINTED ON iffed below, no assignee pletion of this form is NO		e patent. If an assi an assignment.			document has been filed for
Please check the appropr	riate assignee category or	categories (will not be p	rinted on the patent):	☐ Individual ☐	Corporat	ion or other private gr	oup entity Government
Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies			b. Payment of Fee(s): (I A check is enclose Payment by credit The Director is her overpayment, to D	d. card. Form PTO-20 eby authorized to cl	38 is atta	ached. required fee(s), any de	shown above) eficiency, or credit any an extra copy of this form).
5. Change in Entity Sta	itus (from status indicate is SMALL ENTITY stati		☐ b. Applicant is no		ATT EN	TITY -1-11- 6 27 C	W.D. 1 277(-)(2)
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interest as snown by the	records of the United Sta	nes ratent and Trademan	Conice.				
Authorized Signature				Date			
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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



# UNITED STATES PATENT AND TRADEMARK OFFICE

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KLARQUIST SPARKMAN, LLP			KAUSHAL, SUMESH		
121 S.W. SALMON STREET		ART UNIT PAPER NUMBER			
SUITE #1600 PORTLAND, OR 97204-2988			1633 DATE MAIL ED: 12/17/2009		

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 335 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 335 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Application No. Applicant(s) 10/534 626 FINKEL ET AL. Notice of Allowability Examiner Art Unit Sumesh Kaushal 1633 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 10/16/09. The allowed claim(s) is/are 1-16,48-50 and 54-59. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) $\square$ All b) ☐ Some\* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \* Certified copies not received: \_\_\_\_\_. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) I including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. 

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment/c)

1. 🔲	Notice of	References	Cited	(PTO-892)

- Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08).
- Examiner's Comment Regarding Requirement for Deposit of Biological Material

Paper No./Mail Date	_	
Evaminar's Comment Per	parding Require	ment for Denoei

5. Notice of Informal Patent Application
<ol><li>Interview Summary (PTO-413),</li></ol>
Paper No./Mail Date .

7. X Examiner's Amendment/Comment

8. X Examiner's Statement of Reasons for Allowance

9. ☐ Other .

/Sumesh Kaushal/

Primary Examiner, Art Unit 1633

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Art Unit: 1633

# EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with 11/25/09 on Susan Siegel.

The application has been amended as follows:

#### IN THE CLAIMS

Claim 1, line 9, the text "increased cardiovascular risk or" was deleted before "decreased vascular function"

Claim 54, line 1, the text "claim 1" was replaced with – claim 48 – before ", wherein vascular function".

# IN THE SPECIFICATION

Page 5, line 12, the text "Fig. 4" was replaced with – Fig 4A-B – before "is a set of graphs".

<u>Page 5</u>, line 18, new paragraph — Fig.5A-B show  $\beta$ -galactosidase activity in endothelial progenitor cells.— was inserted.

Page 5, line 19, the text 'Fig.5" was replaced with – Fig.6 – before "is a table"

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# REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: Claims 1-16, 48-50 and 54-59 are free of the prior art of record. The prior art does not teach or suggest a method of diagnosing decreased or increased vascular function (vascular contractility, brachial reactivity or a combination thereof) in a subject by evaluating the number of endothelial progenitor cells in a blood sample derived from the subject. In addition the prior art does not teach or suggest a method of diagnosing increased cardiovascular risk or decreased vascular function in a subject by evaluating the number of senescent endothelial progenitor cells in a blood sample derived from the subject.

The art made of record and not relied upon is considered pertinent to applicant's disclosure: <u>Hill et al</u>, Circulating endothelial progenitor cells, vascular function, and cardiovascular risk. <u>N Engl J Med. 348(7):593-600. 2003</u> (Ref. of record on PTO-1449).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woltach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA OR CANADA) or 571-272-1000.

/Sumesh Kaushal/ Primary Examiner, Art Unit 1633 Sumesh Kaushal Primary Examiner Art Unit 1633